

**FLETCHER ALLEN HEALTH CARE
MCHV CAMPUS
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DEPARTMENT OF LABORATORY MEDICINE – Chemistry Division

TOSOH 2.2 PLUS GLYCOSYLATED HEMOGLOBIN (Hgb A1c)

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REFERENCES:

1. Tosoh 2.2 Plus Operator's Manual, Tosoh Medics, July 1998.
2. Tosoh 2.2 Plus Application Instruction Guide, Tosoh Medics, July 1998.

PRINCIPLE:

The Tosoh 2.2 Plus is a fully automated glycosylated hemoglobin analyzer that utilizes nonporous ion-exchange high performance liquid chromatography (HPLC) for separation of Hemoglobin A1c. This separation is performed rapidly and precisely without interference from Schiff base (labile A1c), lipemia or temperature fluctuations.

A1c analysis is performed without off-line specimen pretreatment or interference from Schiff base (labile A1c). The analyzer dilutes the whole blood specimen with Hemolysis/Wash solution, then injects a small volume of the treated specimen onto the non-porous column. Separation is achieved by utilizing differences in ionic interactions between the cation exchange group on the column resin surface and the hemoglobin components. The hemoglobin fractions are removed from the column by performing a step-wise elution (gradient) using 3 buffers of different salt (ionic) concentrations.

The separated hemoglobin fractions pass through an LED photometer flow cell where the analyzer measures changes in absorbance. The analyzer integrates and reduces the data then calculates the relative percentage of each hemoglobin fraction. A chromatogram displaying the changes in absorbance over time is printed for each sample. A report identifying each peak detected, the relative percent of each peak and retention times accompanies each chromatogram. Each analysis requires 3 minutes.

Two calibrators of known A1c concentration are run once a week for adjustment of the calculation parameters for the determination of A1c.

CLINICAL SIGNIFICANCE:

This assay is used to measure the amount of glycosylated hemoglobin (hemoglobin-glucose complexes) in the blood. Diabetes causes elevated levels of glucose to circulate in the blood. Maintaining normal blood glucose levels is crucial to a diabetic. Careful management of blood glucose levels aids in preventing serious long term complications such as: retinopathy, nephropathy and neuropathy.

A1c gives an accurate index of the mean blood glucose concentration over the past 2 months. A single fasting blood glucose measurement only gives an indication of the patient's immediate past condition (hours) but may not represent the true status of blood glucose regulation.